**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF WISCONSIN**

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JILL A. WHITCOMB,

Plaintiff, Case No. 17-CV-14

v.

THOMAS E. PRICE, M.D.,
Secretary of Health and Human Services,

Defendant.

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**DEFENDANT'S RESPONSE TO PLAINTIFF'S REQUEST FOR JUDICIAL REVIEW**

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Defendant Thomas E. Price, M.D., Secretary of Health and Human Services ("Secretary"), requests that the Court affirm the decision of the Medicare Appeals Council ("the Council") denying coverage for Plaintiff's continuous glucose monitoring system ("CGM"), for the reasons set forth below.

## I. Introduction

Plaintiff, Jill A. Whitcomb, filed this action pursuant to 42 U.S.C. § 1395w-22(g)(5) to seek judicial review of the Secretary's final decision which denied coverage for a CGM. CGMs consist of three components: a disposable sensor, a transmitter, and a receiver. The disposable sensor is positioned subcutaneously under the skin and measures the interstitial glucose levels, the sensor sends the interstitial glucose measurements to the transmitter, and the transmitter relays the measurement to a receiver where Plaintiff may view it. While the present case originated as Plaintiff's request for prior authorization from her Medicare Advantage Organization to obtain a CGM manufactured by Medtronic ("Medtronic MiniMed System"), Plaintiff stated in her opening brief that she has since purchased the Dexcom G4 CGM and now

seeks reimbursement for it and its related supplies. Document 15, FN. 2.[1] Although the Secretary acknowledges that Plaintiff may benefit from using a CGM (whether it be the Medtronic MiniMed System or the Dexcom G4), the evidence shows that these adjunctive devices do not qualify for coverage under a defined Medicare benefit category. Specifically, the evidence shows that the requested CGM at issue does not meet the definition of durable medical equipment ("DME"). Consequently, it does not fall within a defined Medicare benefit category that would permit coverage. Accordingly, the Secretary requests that the Court affirm his final decision because it is supported by substantial evidence in the record and is free from legal error.

## II. Statutory and Regulatory Framework

### A. Overview of the Medicare Advantage Program

The Medicare program, Title XVIII, 42 U.S.C. § 1395 *et seq*., is a federally funded and administered health insurance program for eligible persons who are (1) 65 years of age or older who are entitled to social security retirement benefits, or (2) disabled or have end stage renal disease and are entitled to social security disability benefits. 42 U.S.C. § 1395c. The Secretary administers the Medicare program through the Centers for Medicare & Medicaid Services ("CMS") of the United States Department of Health and Human Services.

The Medicare program is divided into four major components. Part A, the hospital insurance benefits program, provides health insurance coverage for services including, but not limited to, inpatient hospital care, post-hospital care in a skilled nursing facility, and post-hospital home care services. 42 U.S.C. §§ 1395d - 1395i-5; 42 C.F.R. Part 409. Part B, the

[1] According to an invoice submitted by Plaintiff, her costs associated with the DexCom G4 amount to $2,449.00. AR 336-337. It is unclear whether Plaintiff has submitted a formal claim to SecureHorizons for this amount. It is therefore unclear whether she has exhausted her administrative remedies with respect to her request for reimbursement. The Secretary submits that the present case is limited to the denial of Plaintiff's request for preauthorization for the Medtronic MiniMed System since that is the issue that was reviewed and has been administratively exhausted during the administrative process.

supplemental medical insurance benefits program, generally pays for a percentage of certain medical and other health services that are supplemental to the benefits provided by Part A, including, but not limited to, physician services, certain home health services, and outpatient physical and occupational therapy. 42 U.S.C. §§ 1395k and 1395l. Part C, also known as the Medicare Advantage ("MA") program, allows CMS to contract with public and private entities to provide, at a minimum, Medicare benefits to certain Medicare beneficiaries. 42 U.S.C. § 1395w-21 *et seq*. Part D provides prescription drug coverage to qualifying enrollees. 42 U.S.C. § 1395w-101 *et seq*.

The present case arises under Part C as it involves Plaintiff's request that UnitedHealthcare/SecureHorizons ("SecureHorizons"), a Medicare Advantage organization, provide coverage for a CGM.[2] The MA program, formerly known as Medicare + Choice, allows eligible Medicare beneficiaries to enroll in MA plans to receive their Medicare benefits. 42 U.S.C. § 1395w-21 *et seq.*; 42 C.F.R. Part 422. A MA plan refers to the "health benefits offered under a policy or contract by a MA organization that includes a set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan." 42 C.F.R. § 422.2. MA plans may be coordinated care plans, like health maintenance organizations (HMO), medical savings accounts, or private fee-for-service plans. 42 U.S.C. § 1395w-21(a)(2); 42 C.F.R. § 422.4. In this case, Plaintiff was enrolled in AARP MedicareComplete Plus, a MA coordinated care plan offered by SecureHorizons.

All MA plans must provide, at a minimum, basic benefits. Basic benefits include the benefits offered by original Medicare (meaning Medicare Parts A and B). 42 U.S.C. § 1395w-

[2] Plaintiff characterized the present case as arising under Part B. However, because the case involves Plaintiff's request for coverage under her MA plan, the case arises under Part C (although Part B coverage rules apply to the extent that the MA organization relied upon them in determining coverage).

22(a)(1); 42 C.F.R. § 422.100(c)(1). With respect to basic benefits, MA organizations are required to comply with national coverage determinations ("NCDs"), general coverage guidelines included in the Medicare manuals and instructions, and written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered under the MA plan. 42 C.F.R. § 422.101(b). To encourage beneficiaries to enroll in MA plans, many MA organizations offer supplemental benefits, which are benefits that go beyond the benefits offered by original Medicare. 42 U.S.C. § 1395w-22(a)(3); 42 C.F.R. § 422.100(c)(2); 42 C.F.R. § 422.102.

A MA plan's benefits must be set forth in a standardized form, known as the Evidence of Coverage ("EOC"). 42 U.S.C. § 1395w-22(c)(1)(B); 42 C.F.R. § 422.111. CMS provides model EOCs that are used by MA organizations. The MA organizations only alter the model EOCs by adding information regarding their MA plans' specific benefits, cost sharing, and rules governing the receipt of benefits. MA organizations are required to provide EOCs to beneficiaries upon their enrollment and then at least annually thereafter. *Id.* Ultimately, the EOC serves as one of the documents that governs the relationship between an enrollee and the MA organization.

### B. Appeals Process Under Medicare Part C

Like beneficiaries in Original Medicare, enrollees of MA plans have access to a multi-tiered appeals process for when they disagree with a MA organization's determination. An enrollee that disagrees with an organization's determination may ask the MA organization to reconsider its initial decision. 42 C.F.R. § 422.578. The reconsideration is completed by the MA organization. If the MA organization affirms its original decision, the decision is automatically reviewed by an independent review entity ("IRE"). 42 C.F.R. § 422.492. If an enrollee disagrees with the IRE's decision, he or she may request a hearing before an

administrative law judge, provided that the request is made timely and the amount in controversy is met. 42 C.F.R. § 422.600. The amount in controversy for cases involving denied services is the projected value of the service. 42 C.F.R. § 422.600(c). The parties to the ALJ hearing are the enrollee and the MA organization. Any party to the ALJ decision who is dissatisfied with the ALJ decision may request that the ALJ's decision be reviewed by the Council. 42 C.F.R. § 422.608. Finally, any party to the Council's decision may seek judicial review of the Secretary's final decision, provided that the request is timely filed and the amount in controversy is met. 42 C.F.R. § 422.612. For cases filed in 2017, the amount in controversy threshold for judicial review is $1,560.

### C. Overview of Medicare Coverage of Durable Medical Equipment

For items and services to be covered by Medicare, they must be (1) eligible for coverage under a defined benefit category, (2) reasonable and necessary for the diagnosis or treatment of an injury or illness, and (3) not otherwise excluded. 42 U.S.C. §§ 1395k, 1395x, 1395y(a)(1)(A), (B); *see also, Anghel v. Sebelius*, 912 F.Supp.2d 4, 10 (E.D.N.Y. 2012).

The Medicare statute provides coverage for "medical and other health services," which is defined to include durable medical equipment ("DME"). 42 U.S.C. § 1395x(s), (s)(6). The Medicare statute defines DME as follows:

> The term 'durable medical equipment' includes iron lungs, oxygen tents, hospital beds, and wheelchairs…used in the patient's home…[,] whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations) and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories…

42 U.S.C. § 1395x(n).

CMS regulations establish the criteria for DME. *See Medicare Program; Final Rule on Durable Medical Equipment*, 76 Fed. Reg. 70,228, 70,286 (Nov. 10, 2011) (discussing the history of the DME benefit and regulatory criteria for DME). Pursuant to the regulations, DME is specifically defined as:

> …[E]quipment furnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use.
>
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
>
> (3) Is primarily and customarily used to serve a medical purpose.
>
> (4) Generally is not useful to an individual in the absence of an illness or injury.
>
> (5) Is appropriate for use in the home.

42 C.F.R. § 414.202.

CMS has set forth interpretative guidance for these regulations in its Medicare Benefit Policy Manual ("MBPM"), CMS Pub. 100-02, Chapter 15, § 110, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/CMS012673.html. The MBPM, in discussing equipment that is primarily and customarily used to serve a medical purpose states "first-aid or precautionary-type equipment (such as preset portable oxygen units)…are considered non-medical in nature" and, therefore, "are not considered covered DME." *Id.* at § 110.1-B-2. As noted, the statutory requirements for Medicare coverage include the requirement that an item or service be reasonable and necessary for the diagnosis and treatment of an injury or illness. With regard to whether DME is reasonable and necessary in a particular case, the MPBM explains that payment will be barred

"for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case…" *Id.* at § 110.1-C.

In addition to the Medicare statute, regulations, and the MBPM guidance related to determining whether an item or service qualifies for Medicare coverage, the statute authorizes the Secretary to issue binding National Coverage Determinations ("NCDs"). A NCD is "a determination by the Secretary with respect to whether a particular item or service is covered nationally under [the Medicare program]." 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R. § 405.1062(a). In issuing a NCD, the Secretary draws on the expertise of various components of HHS, as well as sectors of the medical and scientific community and other interested parties. *See Medicare Program; Revised Process for Making Medicare National Coverage Determinations*, 68 Fed. Reg. 55,634 (Sept. 26, 2003). NCDs are binding on Medicare's Administrative Contractors ("MACs") that process claims, qualified independent organizations, ALJs, and the Council. 42 C.F.R. § 405.1060(a)(4).

Unlike NCDs, Local Coverage Determinations ("LCD") are coverage determinations that are issued by MACs relating to coverage of items and services within the jurisdiction of a specific MAC. 42 U.S.C. § 1395ff(f)(2)(B). LCDs "specify under what clinical circumstances a service is considered to be reasonable and necessary," and are developed after "consider[ation of] medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community." Medicare Program Integrity Manual ("MPIM"), CMS Pub. No. 100-08, Ch. 13, § 13.1.3 (effective Jan. 1, 2012), http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. LCDs are not binding on ALJs or the Council but should be given substantial deference if applicable to a particular case. 42 C.F.R. § 405.1062. If the Council or an ALJ declines to

follow a LCD, the decision must explain why the policies were not followed. Any such decisions are not precedential. 42 C.F.R. § 405.1062(b).

MACs may also issue guidance in the form of Local Coverage Articles ("Article"), which may address benefit category determinations, coding guidelines, or statutory exclusion provisions pertinent to particular items and services discussed in a related LCD. *See* MPIM, Ch. 13, § 13.1.3.

MA organizations are required to comply with: 1) NCDs; 2) general coverage guidelines included in original Medicare manuals and instructions; and 3) written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under a MA plan. 42 C.F.R. § 422.101(b). Thus, unlike the Council and ALJs, MA organizations must adhere to LCDs and Medicare manuals and instructions.

**D. Overview of Medicare Coverage of CGMs**

Plaintiff's requested CGM is functionally different from a home blood glucose monitor. The requested CGM consists of a disposable sensor, a transmitter, and a receiver, and it acts to continuously measure Plaintiff's interstitial fluid glucose levels, that is, glucose in the fluid surrounding the cells of the tissue beneath the skin. AR 6. Based on the readings, the CGM alerts Plaintiff as to when she should take a home blood glucose reading, i.e. a finger stick reading, to determine if it is necessary to make adjustments to her course of therapy. *Id.* In contrast to a CGM, a home blood glucose monitor measures the glucose level in Plaintiff's blood directly, through the use of a disposable sterile lancet that draws a drop of blood. The blood is then placed on a reagent strip and inserted into the glucose monitor to obtain a blood glucose reading. National Coverage Determination 40.2: Home Blood Glucose Monitors, CMS Pub. No. 100-3 (effective June 19, 2006); Medicare Coverage Database, www.cms.gov/medicare-

coverage-database/indexes/ncd-by-chapter-and-section-index.aspx; AR 923-925. Once the blood glucose reading is read, Plaintiff is able to use the result to make immediate therapeutic decisions, typically whether to increase or decrease insulin medication.

The Medicare statute expressly covers home blood glucose monitors under the DME benefit if there is a reasonable and medically necessary need for the monitors. 42 U.S.C. § 1395x(n). The statute is silent on coverage of CGMs. *Id.* NCD 40.2 discusses coverage for home blood glucose monitors, but is silent also on coverage of CGMs. AR 923-925. National Government Services ("NGS"), the MAC assigned to cover Wisconsin, issued LCD L27231. AR 914-922. While LCD L27231 specifically outlines the criteria for coverage for home blood glucose monitors, it too does not discuss coverage for CGMs. However, in LCD L27231's related policy article, Article A47238, NGS discusses information regarding benefit categories for certain blood glucose monitoring supplies and devices. AR 926-928. Regarding CGMs, NGS explained "continuous glucose monitors (A9276-A9278) are considered precautionary and therefore non-covered under the DME benefit." AR 927. Significantly, this Court has already determined that neither NCD 40.2 nor LCD L27231 provide for coverage for CGMs. AR 229. Because there is no specific coverage for CGMs, it is necessary to turn to CMS regulations and guidance to determine whether Plaintiff's requested CGM may be covered as DME. If the answer is yes, then an inquiry into whether the CGM is reasonable and necessary is appropriate. If the requested CGM may not be covered as DME, then no inquiry into whether it is reasonable and necessary need be performed.

CMS Ruling No. 1682 sheds light onto whether CGMs, like the one Plaintiff is requesting, qualifies as DME. In the ruling, CMS concluded that Medicare Part B "does not cover CGMs approved by the FDA for use as adjunctive devices to compliment, not replace,

information obtained from blood glucose monitors." CMS Ruling No. 1682-R, at 6-7 (Jan. 12, 2017), https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf. While CMS recognizes that CMS Ruling No. 1682 was issued after the present litigation was initiated, it is useful in understanding CMS's overall policy scheme regarding CGMs and further explains NGS's use of the term "precautionary." CMS Ruling No. 1682 explains "[i]n our view, such devices are not used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, and therefore, have not been covered under Medicare because they are not considered to serve the medical purpose of making diabetes treatment decisions." *Id.* at 7. The Ruling goes on to note that the FDA has recently approved expanding the indications of one CGM device that is technologically advanced to the point that it is able to replace blood glucose monitors for making diabetes treatment decisions. *Id.* CMS refers to CGMs that are approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions as "therapeutic CGMs" and such therapeutic CGMs fall within the Medicare Part B benefit category of DME, if they also meet other statutory criteria for coverage, *e.g.*, the reasonable and necessary criteria under 42 U.S.C. § 1395y(a)(1)(A). Here, Plaintiff is not requesting coverage for a therapeutic CGM.

## III. Statement of Facts

### A. Medical Facts Relevant to Plaintiff's Request of a CGM

Plaintiff is diagnosed with Type I diabetes. AR 5, 25, 148, 285, 472. She has a complication known as hypoglycemia unawareness, which means that she is unable to detect sudden drops in her insulin levels. *Id.*; AR 249, 283, 472. In light of her condition, Plaintiff sought preauthorization for a CGM (HCPCS Codes A9276, A9277, A9278) that was prescribed

by her treating provider. *Id.* According to Dr. David Smith, he prescribed a CGM for Plaintiff because she frequented the emergency room as a result of her hypoglycemic unawareness. AR 148. Since Plaintiff has been using a CGM, Dr. Smith notes that the number of times she has needed emergency care has been reduced. *Id.*

**B. Procedural History**

On April 14, 2011, Plaintiff requested that SecureHorizons authorize her to obtain a CGM (HCPCS codes A9276, A9277, and A9278). AR 474. On May 13, 2011, SecureHorizons denied Plaintiff's request because long term use of CGMs are not covered by Medicare or her MA plan. AR 549. In its June 10, 2011 redetermination decision, SecureHorizons upheld its denial. AR 567-568. SecureHorizons stated that CGMs are considered precautionary, and therefore, not covered under Medicare's DME benefit as noted in Article A47238. *Id.* Consequently, SecureHorizons was not required to authorize coverage for the requested CGM. *Id.* Similarly, on June 24, 2011, the IRE also determined that SecureHorizons did not have to cover the CGM because it is a precautionary device. AR 585-586. Plaintiff challenged the denial of coverage by requesting a hearing before an administrative law judge ("ALJ").

Hearings were held on October 15, 2012, and January 17, 2013. AR 233-314. On February 6, 2013, the ALJ issued a decision ordering SecureHorizons to cover the requested CGM. AR 356-366. The ALJ acknowledged that Article A47238 explicitly stated that CGMs are not covered under Medicare's DME benefit. However, the ALJ declined to follow the guidance set forth in Article A47238. AR 365. Instead, the ALJ found that coverage was available under NCD 40.2 and LCD L27231, even though both the NCD and LCD are silent on coverage of CGMs. AR 365-366.

SecureHorizons appealed the ALJ's decision to the Council. AR 349-354. In response, on August 23, 2013, the Council reversed the ALJ, finding that neither NCD 40.2 nor LCD L27231 provided coverage for CGMs. AR 322-330. Moreover, the Council held that LCD L27231 incorporated Article A47238 and that the record did not support a basis for the ALJ to disregard the article. AR 327-328. Accordingly, the Council held that SecureHorizons was not required to cover Plaintiff's requested CGM. Plaintiff requested that the Council reopen its decision. This request was denied on November 1, 2013. AR 316-321. In denying the request, the Council informed Plaintiff that in order for an item to qualify as DME, it must meet the regulatory requirements. AR 318. The Council added that since CGMs were considered precautionary devices, they did not qualify as DME. *Id.*

Plaintiff appealed the Council's decision to this Court. In its May 26, 2015 decision, the Court agreed with the Council that NCD 40.2 and LCD L27231 do not provide coverage for CGMs. AR 212-221. However, the Court disagreed that LCD L27231 incorporated Article A47238. AR 219-220. The Court noted that articles were not developed with notice and comment and could not be challenged like LCDs. *Id.* Thus, the Court concluded that articles serve the very limited purpose of setting forth non-coverage information, like coding and payment information. *Id.* In light of their limited purpose, the Court further found that articles do not qualify as CMS guidance deserving of substantial deference under 42 C.F.R. § 405.1062(a). AR 220. Ultimately, the Court found that "the question is whether a continuous glucose monitor is reasonable and necessary for [the enrollee] and not otherwise excluded" and remanded the case back to the Secretary "to assess this case under the proper legal standard." *Id.*

In response to the Court's decision, on August 28, 2015, the Council remanded the case to the ALJ for a determination whether the requested CGM qualified as DME. AR 199-203. The

Council stated that in analyzing coverage for an item or service, the relevant inquiry must first determine whether the item or service falls within a statutory benefit category. AR 202. If it does, the adjudicator then decides if the item or service is reasonable and necessary. *Id.* In this case, the Council pointed out that the ALJ's focus was on whether the requested CGM was reasonable and necessary. He did not address whether the CGM met the definition of DME. *Id.* Thus, the Council instructed the ALJ to:

> [C]onsider whether the Policy Article constitutes binding guidance for the Medicare Advantage Plan, pursuant to 42 C.F.R. section 422.101(b)(3). Only if the ALJ determines that the CGM systems meet the definition of DME, then should the ALJ analyze whether the CGM system is medically reasonable and necessary for the enrollee in this case, pursuant to the District Court's Order.

*Id.*

After presiding over a new hearing, on October 14, 2015, the ALJ found that the requested CGM qualified as DME. AR 20-35, 1152-1202. In addition to finding that the CGM qualified for coverage under the DME benefit category, the ALJ found that the CGM was reasonable and necessary for Plaintiff. AR 31-33. The ALJ noted that he was not required to give substantial deference to Article A47238 because it is not a coverage determination. AR 33. The ALJ also noted that SecureHorizons was not bound by Article A47238 because it was not the type of guidance referred to under 42 C.F.R. § 422.101(b)(3). *Id.* Finally, despite this Court's ruling that NCD 40.2 and LCD L27231 did not provide coverage for CGMs, the ALJ found that they did not differentiate between home blood glucose monitors and CGMs. AR 33-34. The ALJ thus found that coverage was available for CGMs under NCD 40.2 and LCD L27231. *Id.*

SecureHorizons again appealed the ALJ's decision to the Council. AR 82-86. SecureHorizons argued that the specific CGM for which Plaintiff sought preauthorization, *i.e.* the Medtronic MiniMed System, is not covered under the Medicare DME benefit because it is a precautionary device that should not be used to make therapeutic decisions. AR 83-84. SecureHorizons pointed out that the FDA approval for the requested CGM stated, among other things, that it must be used with a blood glucose meter, no treatment decisions should be made or changed based on the results of the CGM's readings, and the results of the CGM's readings must be confirmed by a finger stick test. AR 84, 102. SecureHorizons acknowledged that Plaintiff had since obtained a Dexcom G4. AR 84. However, SecureHorizons added that the Dexcom G4 was also a precautionary device. *Id.* To support its position, SecureHorizons submitted the Dexcom G4's FDA approval which stated the readings from this system are not intended to replace the information obtained from a standard home blood glucose monitor. AR 84, 104. Rather, the Dexcom G4 is intended to compliment the information obtained from the traditional test. *Id.* In response, Plaintiff argued that the CGM is the standard of care for Type I diabetics with hypoglycemia unawareness. AR 76-77. Plaintiff acknowledged, though, that CGMs need to be used in connection with finger stick tests. *Id.*

After reviewing the record, the Council concluded that CGMs do not qualify for coverage because they are not DME, which means that CGMs, even if considered medically necessary, are not covered by Medicare because they do not fit in a defined benefit category. AR 9. The Council explained that DME must be primarily and customarily used for a medical purpose. AR 10. The Council stated that CGMs are not primarily and customarily used for a medical purpose because they are precautionary items. AR 10. While the Council acknowledged that the term precautionary is not statutorily defined, the Council found that this means that the device itself

must be used for a medical purpose. Here, the Council found that the requested CGM was not used for a medical purpose because it did not measure glucose in the blood and therapeutic decisions were not supposed to be made based on its readings, without first confirming blood glucose levels with a finger stick test. In other words, the CGM was not a substitute for finger stick tests. Rather, the CGM simply provided an added precaution. AR 10. The Council added that the ALJ erred by ignoring this Court's holding that neither NCD 40.2 nor LCD L27231 provide coverage for CGMs. AR 10.

Plaintiff appealed the Council's second decision to this Court. That appeal is the subject of the present litigation.

**C. SecureHorizons Evidence of Coverage and Coverage of CGMs**

Diabetic supplies are covered by SecureHorizons as outlined in its internal coverage policies and its members' EOCs. As discussed above, enrollees in a MA plan, such as Plaintiff, receive an EOC that sets forth the covered benefits under a MA plan. Here, Plaintiff received SecureHorizons' EOC for her MA plan, AARP MedicareComplete Plus. AR 932-1126. The EOC specifically advises enrollees that services, supplies, and equipment must be provided according to the coverage guidelines established by Medicare and be medically necessary. AR 957. Indeed, the EOC highlights that it excludes services that are not reasonable and necessary according to the standards set forth by original Medicare. AR 1002. Thus, consistent with original Medicare, SecureHorizons covers items such as blood glucose monitors, test strips, lancets, and glucose-control solutions used to check the accuracy of the testing strips. AR 982.

SecureHorizons' internal policy that explains the coverage described in the EOC is its Diabetic Management, Equipment and Supplies Policy. AR 905-913. Coverage for home glucose monitors mirrors the coverage requirements outlined in NCD 40.2 and LCD L27231.

906-907. Section 5 of the policy specifically discusses continuous glucose monitoring systems. AR 907. This portion of the policy acknowledges that Medicare does not have a NCD relating to the short-term use of CGMs and that only one contractor has a LCD for the short-term use of professional-grade CGMs (as opposed to personal CGMs like the one requested by Plaintiff). *Id.* Given the sparse coverage information relating to the short-term use of professional-grade CGMs, SecureHorizons decided that it would cover the short-term use of professional-grade CGMs for all of its enrollees. *Id.*

SecureHorizons' policy notes that CGMs are intended to supplement, not replace, standard self-monitoring of blood glucose checks performed with a finger stick. AR 907-908. The purpose of using a CGM is to obtain values over a short period of time so that the treating practitioner can adjust treatment regimens depending on the data and patterns that it might show. *Id.* Further, the policy recommends that values obtained via CGM be validated through the use of a metered blood glucose monitor. *Id.* Because the policy recognizes the limitations of using CGMs, it goes on to state, "*Long term use or frequent use of continuous glucose monitoring will be* ***denied as not medically necessary.***" *Id.* (emphasis in original). Further, the policy states that because no LCDs for long-term use of CGMs exist, SecureHorizons will adhere to applicable articles, such as Article A47238. Overall, SecureHorizons' coverage policy adheres to the coverage criteria set forth by Medicare. Accordingly, it does not cover the long-term use of a CGM like the Medtronic MiniMed System or the Dexcom G4.

## IV. Argument

### A. Standard of Review

Once the Secretary has issued his final decision regarding a Medicare claim, judicial review of that decision is available under 42 U.S.C. § 405(g); 42 U.S.C. § 1395w-22(g)(5)

(setting forth the requirements for judicial review of claims involving Medicare beneficiaries enrolled in MA plans). Section 405(g) grants the Court "the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing." Under this framework, the Court's task is limited to determining whether the Secretary's final decision is supported by substantial evidence and is free from legal error. *Wood v. Thompson*, 246 F.3d 1026, 1029 (7th Cir. 2001). Substantial evidence means "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971). To determine if substantial evidence exists, the Court reviews the administrative record but does not re-weigh the evidence, resolve conflicts, decide issues of credibility, or substitute its judgment for the Secretary's. *Clifford v. Apfel*, 227 F.3d 863, 869 (7th Cir. 2000). If the Secretary's factual findings are supported by substantial evidence, they are conclusive. 42 U.S.C. § 405(g); *Wood*, 246 F.3d at 1029. However, this does not mean that the Court should simply rubber-stamp the Secretary's decision. *Clifford*, 227 F.3d at 869. Overall, absent legal error, the reviewing court must affirm a decision based on substantial evidence, even if the court would have decided the case differently. *Delgado v. Bowen*, 782 F.2d 79, 83 (7th Cir. 1986); *see also Wilkins v. Sullivan*, 889 F.2d 135, 140 (7th Cir. 1989) ("It is precisely this type of decision - made within the context of an extremely technical and complex field - that courts should leave in the hands of the expert administrators."); *Cutlip v. Sec'y of Health & Human Servs.*, 25 F.3d 284, 286 (6th Cir. 1994) ("If the Secretary's decision is supported by substantial evidence, it must be affirmed even if the reviewing court would have decided the matter differently, and even if substantial evidence also supports the opposite conclusion") (citations omitted).

### B. The Secretary's Denial Of Coverage Is Supported By Substantial Evidence And Should Be Affirmed

The Secretary's final decision denying Medicare coverage for the requested CGM is supported by substantial evidence and is free from legal error. Accordingly, the Court should affirm the Secretary's final decision.

As discussed above, in order for an item or service to be covered under Medicare, the item or service must fall within a defined benefit category, be reasonable and necessary for the diagnosis or treatment of an injury or illness, and must meet all applicable statutory and regulatory requirements. 42 U.S.C. §§ 1395k, 1395x, 1395y(a)(1)(A); 68 Fed. Reg. at 55,635 ("Medicare payment is contingent upon a determination that a service meets a benefit category, is not specifically excluded from coverage, and the item or service is 'reasonable and necessary.'"). In this case, as the Council correctly found, the requested CGM does not fall within a defined benefit category, and as a result, it is not eligible for coverage.

The Council's decision is consistent with CMS's established criteria for DME. The Medicare statute expressly permits coverage for "medical and other health services," which includes coverage for DME. 42 U.S.C. §§ 1395k, 1395x(s), 1395x(s)(6). DME is statutorily defined to permit coverage for home blood glucose monitors. However, the statute does not provide coverage for CGMs, which are functionally different from blood glucose monitors. 42 U.S.C. § 1395x(n). Because CGMs are not explicitly covered by the Medicare statute as are blood glucose monitors, the Secretary considered whether the requested CGM satisfied the regulations governing DME.

Under 42 C.F.R. § 414.202, in order for equipment to be covered as DME, it must be able to withstand repeated use, have an effective life expectancy of at least three years, primarily and customarily serve a medical purpose, generally not be useful to an individual in the absence of an

illness or injury, and be appropriate for use in the home. In fleshing out whether a specific item serves a medical purpose, the Secretary explained in the MBPM that precautionary equipment is considered nonmedical, and therefore, it is not covered as DME. MBPM, CMS Pub. 100-02, Ch. 15, § 110; *See LCD Complaint: Glucose Monitors (L11530/L33822 and Local Coverage Articles A33614/A52464)*, DAB No. 2782 at 12 (2017), 2017 WL 1838026 (noting that a determination regarding whether an item is precautionary relates to determining whether it is primarily and customarily used for a medical purpose). While the MBPM is not the equivalent of a regulation promulgated after a notice and comment period, the MBPM is still deserving of substantial deference because it includes the Secretary's informed interpretation of the Medicare regulations. *Paragon Health Network v. Thompson*, 251 F.3d 1141, 1145 (7th Cir. 2001), *citing Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994) (finding that an agency's interpretation of its regulations is "entitled to controlling weight unless it is plainly erroneous or inconsistent with the regulation."). Consequently, when determining whether an item qualifies as DME, this Court should give substantial deference to the Secretary's long-standing policy that precautionary equipment is generally not covered under the DME benefit category because it is not primarily and customarily used to serve a medical purpose. Since Article A47238 accurately reflects the Secretary's policy as set forth in the MBPM, it too should be afforded deference.

Recognizing that the Secretary is entitled to define the DME benefit category as not including precautionary equipment, this Court should uphold the Secretary's final decision denying coverage for Plaintiff's requested CGM. The record is replete with evidence establishing that the requested CGM is a precautionary device. Indeed, the FDA guidance for the Medtronic MiniMed System specifically states that it cannot, and should not, be used to make therapeutic decisions. AR 84, 102. It further states that any readings obtained via the

system must be confirmed with a finger stick test. *Id.* Similarly, the FDA approval for the DexCom G4 makes clear that it too must not be used by itself when making therapeutic decisions. Instead, the FDA stated that it must be used in conjunction with a blood glucose monitor. AR 84, 104. Given that the FDA guidance for these devices establishes that they cannot be relied upon to make treatment decisions, the Secretary (and SecureHorizons) properly concluded that CGMs are precautionary devices that do not qualify for coverage as DME.

Moreover, the articles written by professional medical associations and other third-party organizations support the Secretary's position that CGMs are precautionary devices. For example, the American Diabetes Association ("ADA") recognized that CGMs can be a supplemental tool for managing hypoglycemia unawareness. Record at 18, ADA Position Paper. The ADA added that CGMs must be calibrated using a traditional home blood glucose monitor and that treatment decisions must still be made using home blood glucose monitors. *Id.* Additionally, a study published in the *Journal of Diabetes Technology & Therapeutics* directed participants to "use CGM data as an adjunct to, and not a replacement for [self-monitoring of blood glucose] finger sticks when making diabetes-related treatment decisions (*e.g.* insulin dose modifications)" and concluded that the accuracy of CGMs does not yet equal the accuracy of self-monitoring of blood glucose. Record at 18, Attachment 1. Thus, even the professional organizations upon which Plaintiff relies agree that CGMs should not be used to make treatment decisions. In light of the consistent statements emphasizing that treatment decisions should not be made using a CGM alone, Plaintiff's argument that a CGM is the *only* mechanism by which she can control her diabetes is unpersuasive.

Overall, the Secretary's guidance set forth in the MBPM should be afforded substantial deference. It is through this interpretive guidance that the Secretary explains how he interprets

the DME regulations. The Secretary's policy is that precautionary-type equipment is considered non-medical, and therefore, it does not meet the regulatory requirement that DME be primarily and customarily used to serve a medical purpose. This is not to say that the Secretary does not agree that a CGM may benefit Plaintiff. But, whether a device serves a benefit is not the dispositive question when determining coverage under Medicare. As previously stated, Medicare is a defined benefits program. As such, coverage is only available for items that meet *all* of the coverage criteria, *i.e.* they fall under a defined benefit category, they are reasonable and necessary, and they are not otherwise excluded. Here, while the requested CGM may be reasonable and necessary, this alone does not result in coverage because it is not DME as defined by Medicare.[3]

**C. Plaintiff's Miscellaneous Arguments Lack Merit**

Plaintiff makes a number of miscellaneous arguments in an effort to persuade this Court to reverse the Secretary's final decision. These arguments lack merit. For example, Plaintiff argues that other unspecified Medicare beneficiaries have received coverage for CGMs so she, too, should receive coverage. This argument is unavailing for two primary reasons. First, Plaintiff has not specified the cases to which she refers. Therefore, the Secretary lacks sufficient information to respond. There is simply no way to know, for example, whether the unspecified beneficiaries were members of MA plans that provided supplemental coverage for CGMs and that is why they received coverage. Also, there is no way to know why a MA organization might not have appealed an ALJ decision. Thus, this Court should not be convinced that Plaintiff's request for coverage should be granted because others may have received CGMs. Second, and equally if not more important, ALJ decisions are only binding on the parties to that decision. In

[3] In contrast, the Secretary has determined that Medicare will cover therapeutic CGMs as described in CMS Ruling 1682. To date, the DexCom 5 qualifies as a therapeutic CGM.

other words, ALJ decisions have no precedential effect. 42 C.F.R. § 405.1062(b). Consequently, whether an ALJ ordered a MA organization to cover a CGM for one of its enrollees has no bearing on the present case.

Plaintiff also argues that the Secretary's final decision should be reversed because her treating provider ordered a CGM for her to use. Plaintiff is essentially arguing that the requested CGM should be covered because her physician opined that it will benefit her. As discussed above, this argument fails because medical necessity does not govern Medicare coverage alone. Rather, items and services must also fall under a defined benefit category and not be otherwise excluded. The fact that a device might provide a medical benefit is insufficient to warrant coverage. Furthermore, it is the Secretary who is entitled to determine whether an item or service is reasonable and necessary when determining coverage, not a treating physician. *State of N.Y. on behalf of Bodnar v. Sec'y of Health & Human Servs.*, 903 F.2d 122, 125 (2d Cir. 1990) ("The Medicare statute unambiguously vests final authority in the Secretary, an no one else, to determine whether a service is reasonable and necessary, and thus whether reimbursement should be made."). In any event, regardless of whether the requested CGM is medically necessary, the Secretary has determined that it does not fall within a defined benefit category. As a result, no coverage for the CGM is available.

Plaintiff's argument that the vast majority of commercial insurance plans cover CGMs is also unavailing. Whether commercial insurance plans cover CGMs for their enrollees is irrelevant. This case is about whether Medicare, a defined benefits program created by Congress, covers CGMs. Moreover, Plaintiff has not submitted any credible evidence to support this claim. Plaintiff relies on her treating physician as the basis to state that the majority of commercial plans cover CGMs.

## V. Conclusion

The Secretary's final decision is based on the correct application of the Medicare guidelines covering CGMs. Accordingly, the Secretary respectfully requests that this Court affirm his final decision as it is supported by substantial evidence and is free from legal error.

Respectfully submitted,

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